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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,946	11/20/2006	Amit Gefen	GEFENS	7525
1444 7590 11/12/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303				
EXAMINER				
ROBINSON, JAMES MARSHALL				
ART UNIT		PAPER NUMBER		
3772				
MAIL DATE		DELIVERY MODE		
11/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,946

Applicant(s)

GEFEN ET AL.

Examiner

James M. Robinson

Art Unit

3772

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18-23, 27, 38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18-23, 27, 38 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to amendments/arguments filed 8/3/2009. Currently claims 16, 18-23, 27, 38 and 40-42 are pending; claims 16, 18-23, 27, 38 and 40-41 have been amended. Claims 17, 24-26, 28-37 and 39 have been cancelled. Claim 42 has been added. Amendments to the Specification and Drawings have been entered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "said jaw clasps" in the second line of the last clause. There is insufficient antecedent basis for this limitation in the claim. This recitation renders the claim indefinite because only a single jaw clasp is positively recited. As such, it is unclear how the device actually achieves the intended use of wherein said collar is adapted for restricting the motion of the head and neck, while simultaneously maneuvering said jaw clasps attached to the jaw, in a forward and slightly downward direction such that airway maintenance with cervical spine control is provided.

With respect to claim 42, the recitation --wherein said jaw clasp forms a fitting element-- renders the claim indefinite. The limitation of one structure (i.e. jaw clasp)

"forming" another structure (i.e. fitting element) is vague and indefinite. Under what precise circumstance does the jaw clasp "form" the fitting element? Is this an attempt to claim that these elements are indecipherable? Are these elements one? Or does the jaw clasp require manipulation in order to "form" the fitting element? As best as can be understood by examiner, if the jaw clasp forms a fitting element, then the jaw clasp is effectively the fitting element. In order to further prosecution the claim will be examiner as if the jaw clasp is the fitting element. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 16, 18-23, 27, 38 and 40-42 rejected under 35 U.S.C. 102(b) as being anticipated by Nagata et al. (US 5575763).

Nagata discloses a cervical collar (1) for restricting the motion of the head and neck, comprising a rigid motion- restricting frame (2) attached to said head, a jaw clasp (5) attachable to the jaw of said patient (col 4 ln 47-53); additionally comprising a restrictor member (1b) restricting the motion or location of the jaw clasp relative to the rigid frame; wherein the restrictor (1b) limits the distance between the rigid frame and the jaw clasp; wherein the restrictor (1b) limits the direction of motion between the rigid frame and the jaw clasp; additionally comprising a lock member (10) preventing the

backward motion of the jaw clasp relative to the rigid frame; wherein said rigid structure is formed essentially of one collar wrapped around the head and neck (col 3 ln 24-27); wherein said rigid structure is formed essentially of several parts (fig. 1) connected together to fit a specific patient; wherein said holes (2b) or dents allow access to the ears of the patient (fig. 3a); wherein said holes or dents allow access to the front of the neck of the patient (fig. 6); additionally comprising a chin lift collar (1e) wherein holding point is the chin, gum, or any other member of the oral cavity; a jaw clasp (9) useful for performing the jaw- thrust maneuver motion of the jaw to maintain open airways comprising; a plurality of movable fitting elements (fig. 11) adapted to fit the jaw tightly; and, b. a plurality of movable mover elements (9a, 9b) adapted to move the jaw; additionally comprising at least one extrusion (1b) adapted to apply force against resistance of the muscles and to cause forward movement localized at both sides of the jaw; wherein the jaw-thrust maneuver motion is provided by a means of an adjustable knob (6) comprising an inside portion facing the angles of the mandible as holding points and an outside portion maneuverable by the care giver; wherein said inside portion of the adjustable knob comprising a rest (2c) and a bolt (9c), such that an accommodating-pushing groove (7) is provided; said accommodating-pushing groove (7) is adapted to concurrently accommodating the mandible angle while pushing it anteriorly towards the direction of the chin, i.e., in the opposite direction of cervical spin. With respect to claim 42, as best as can be understood, jaw clasp (5) forms a fitting element (5).

The recitation of claim 1 -- wherein said collar is adapted for restricting the motion of the head and neck, while simultaneously maneuvering said jaw clasps attached to the jaw, in a forward and slightly downward direction such that airway maintenance with cervical spin control is provided -- is treated as an intended use recitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. The jaw clasp of the Nagata is clearly capable of achieving the intended use as claimed in light of column 5, lines 10-13: "VELCRO™ fastener is preferably affixed to the internal surfaces of the front supporting portions 1b so that the location of the cheek brace pads 5 (which examiner relies upon as jaw clasp) can be adjusted. It is clear from figures 3a, 3b, 3c, and column 4, line 54 through column 5 line 13 that the jaw clasps of Nagata are intended to be highly adjustable and therefore capable of being "maneuvered in downward direction". With respect to the claim 42 recitation -- adapted to specifically fit the shape of the jaw including the horizontal body portion and the perpendicular Ramus portion -- the recitation is considered an intended use limitation. The same rationale with respect to jaw clasp adjustability as taught by Nagata applies.

Nagata teaches all the elements of the claimed invention; see rejection above. The method for performing a device aided thrust maneuver would have resulted from the normal use of the airway protector including immobilizing the head of the patient (col 1 ln 43-60); clasping the external portion of the mandible (col 2, ln 35-48) by means of a airway protector; maneuvering said clasped mandible (col 3 ln 49-60) forward and slightly downward; in the manner that airway maintenance with cervical spin control is provided.

Response to Arguments

4. Applicant's arguments filed 8/3/2009 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., restrain the mandible) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Nagata does not even intend to maneuver jaw clasps in a forward and slightly downward direction, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The recitation of claim 1 -- wherein said collar is adapted for restricting the motion of the head and neck, while simultaneously

maneuvering said jaw clasps attached to the jaw, in a forward and slightly downward direction such that airway maintenance with cervical spin control is provided -- is treated as an intended use recitation. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. The jaw clasp of the Nagata is clearly capable of achieving the intended use as claimed in light of column 5, lines 10-13: "VELCRO™ fastener is preferably affixed to the internal surfaces of the front supporting portions 1b so that the location of the cheek brace pads 5 (which examiner relies upon as jaw clasp) can be adjusted. It is clear from figures 3a, 3b, 3c, and column 4, line 54 through column 5 line 13 that the jaw clasps of Nagata are intended to be highly adjustable and therefore capable of being "maneuvered in downward direction.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772